See attached form for additional information.

Interagency Report Control No.:

NOV 18 2005

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 16-R-0029

CUSTOMER NUMBER: 55

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Boehringer Ingelheim Pharmaceuticals Inc 900 Ridgebury Road

P.O. Box 368 Ridgefield, CT 06877

Telephone:

(b)(6), (b)(7)c

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

(b)(2)High, (b)(7)f

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )					
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	47	59	19	55	133
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	87	4	149	240
7. Hamsters					
8. Rabbits					
9. Non-human Primates	135	72	37	46	155
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incoming brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)

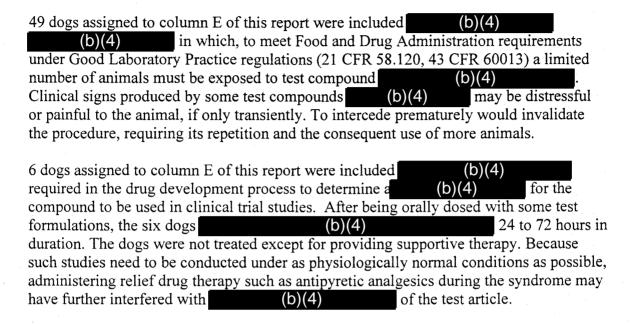
DATE SIGNED

1.7.

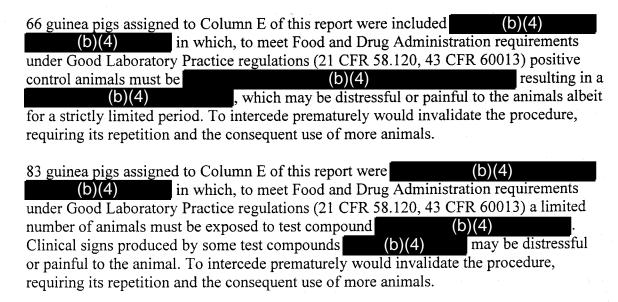
(B)(6) (B)(7)(c)

## Facility Registration Number: 16-R-0029

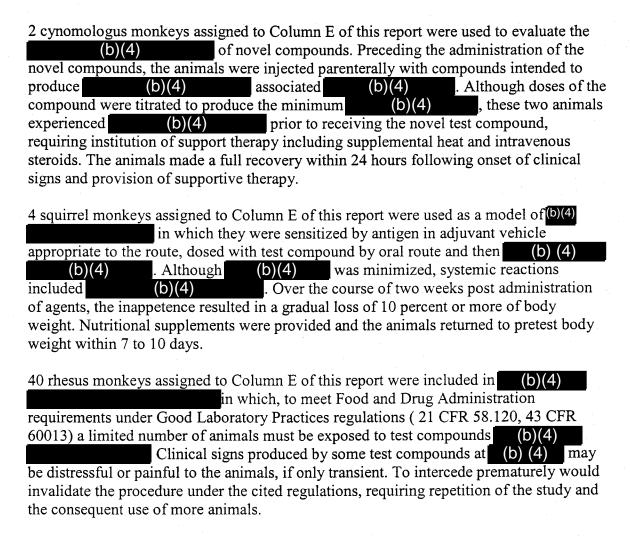
E4



E6



E9





Elizabeth Goldentyer, D.V.M.
Regional Director - Animal Care
United States Department of Agriculture
Animal and Plant Health Inspection Service
Eastern Region Office
900 Main Campus Drive, Suite 200
Raleigh, NC 27606-5213

Boehringer Ingelheim Pharmaceuticals Inc.

December 20, 2005

RE: Addendum to 2005 Annual Report, Certificate Number 16-R-0029

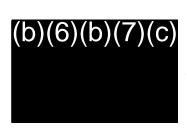
Dear Dr. Goldentyer:

This letter is submitted as an addendum to the 2005 Annual Report of Research Facility, Certificate Number 16-R-0029 (Attachment 1) in response to the letter from your office, dated December 12, 2005 (Attachment 2).

The federal regulations cited in support of animals reported in Column E of the report, as required by 9 CFR 2.36 (b) (7), contained an error. The correct citation is 21 CFR 58.120 and 43 FR 60013. The 43 FR 60013 component of this citation refers to the 1978 Federal Registry announcement that was the original source of 21 CFR 58.

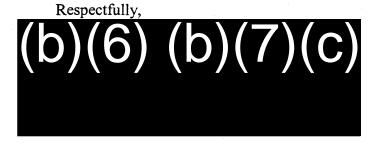
Compliance with 21 CFR 58 is intended to assure the quality and integrity of safety data submitted in support of applications for research or marketing permit for pharmaceuticals regulated by the Food Drug Administration and required by the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

The animals reported under Category E in our annual report for which the above citation was provided in support of their use in nonclinical laboratory studies, are defined in 21 CFR 58.3 (i) as test systems. In accordance with 21 CFR 58.3(d) "Nonclinical laboratory study means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety." In compliance with those regulations, test articles must be administered at sufficiently high dose levels to determine what the highest dose that can be administered safely to the test system without eliciting (b)(4). In order to determine the highest safe dose level, it is necessary to determine (b)(4) in the test system. (b)(4)



900 Ridgebury Rd/P.O. Box 368 Ridgefield, CT 06877-0368 Telephone (203) 798-9988 are determined not only by clinical signs but also by histological changes that may occur as the result of administration of the test article to the test system. Because the use of other drugs such as anti-inflammatory agents or analgesics might cause reversal of the histological (b)(4) of the test articles or induce their own inherent (b)(4) or drug-drug interactions, they could not be administered to the following test systems included in the explanations for Column E entries: 49 dogs, 149 guinea pigs and 40 rhesus monkeys. As a result, animals that experienced more than momentary pain or distress as a side effect of the test article administration were provided either supportive fluid therapy, nutritional supplements or were euthanized when their physiological condition exceeded IACUC approved humane endpoints. The remaining 6 dogs, 2 cynomolgous monkeys, 4 squirrel monkeys included in the Column E entries were provided supportive therapy as described in the original attachments to our 2005 Annual Report of Research Facility.

Thank you for this opportunity to update and clarify our 2005 Annual Report of Research Facility, Certificate Number 16-R-0029.



Attachments - 2

This letter contains confidential information and must be withheld from production under the Freedom of Information Act pursuant to FOI Exemptions 3 and 4.